K091673

Special 510(k) Premarket Notification
GE LightSpeed ACT FP16 Modification
Revised June 15, 2009

JUN 24 2009

Attachment B:

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

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GE Healthcare, P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems, LLC doing business as GE Healthcare
3000 N. Grandview Blvd.
Waukesha, WI 53188

Contact Person: Allen Schuh, Regulatory Affairs Manager
9900 Innovation Drive, Mail Stop RP2138
Wauwatosa, WI 53226

Date Prepared: June 16, 2009

2. Device Name: GE LightSpeed ACT FP16
Computed Tomography X-Ray System, 21 CFR 892.1750, 90J--AK

3. Marketed Device: GE HiSpeed X/i Smart Gantry Option

4. Device Description: The GE LightSpeed ACT FP16 is a modified CT system intended to be located in close proximity to a GE Innova 4100 Single Plane Digital Fluoroscopic Imaging system utilizing a single patient table which can be configured for interventional x-ray or CT imaging procedures. This modification allows the patient to remain on the x-ray table which can be quickly configured for CT scanning via a movable gantry. Both the CT and X-ray systems are used separately, one at a time, in accordance with their respective indications for use.

5. Indications for Use: When configured as a CT System, the GE LightSpeed ACT FP16 is indicated for head and whole body X-ray computed tomography applications. When configured as a fluoroscopic system, the GE LightSpeed ACT FP16 is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, cardiology, diagnostic and interventional procedures, and optionally, rotational imaging procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology and is not intended for mammography applications.

6. Comparison with Predicate Device: GE LightSpeed ACT FP16 is substantially equivalent in terms of safety and effectiveness to the GE HiSpeed X/i Smart Gantry Option (K012385). Both systems utilize a movable CT gantry to scan the patient while placed on a stationary table. They have the same technological characteristics, are comparable in key safety and effectiveness features, utilize similar design, construction, and materials and share the same intended use and clinical purpose.

Section b):

1. Non-clinical Tests: The modifications have been evaluated for conformance to specifications and overall performance as well as for thermal, electrical, radiation and mechanical safety as part of the design verification by employees of the manufacturer and by an independent test agency. The product has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required. Verification of conformance to specifications for the modification was completed with bench testing and imaging phantoms on a fully configured installation. Performance of the equipment movements, user controls and status display was easily evaluated with test equipment and test personnel familiar with clinical practice and procedures.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms to 21 CFR 820, ISO 9001 and 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Therefore, it is the opinion of GE Healthcare that the GE LightSpeed ACT FP16 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2009

GE Medical Systems LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLS
1394 25th Street NW
BUFFALO MN 55313

Re: K091673
Trade/Device Name: GE LightSpeed™ ACT FP16 Modification
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, JAA
Dated: June 5, 2009
Received: June 9, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment E

Indications for Use

510(k) Number (if known): K091673

Device Name: GE LightSpeed™ ACT FP16 Modification

Indications For Use of GE LightSpeed™ ACT FP16 when configured as a CT System:

The GE LightSpeed™ ACT FP16 is indicated for head and whole body X-ray computed tomography applications.

Indications For Use of GE LightSpeed™ ACT FP16 when configured as a Fluoroscopic System:

GE LightSpeed™ ACT FP16 is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, cardiology, diagnostic and interventional procedures, and optionally, rotational imaging procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology and is not intended for mammography applications.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091673